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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/711,339	09/06/1996	ALFRED BINGGELI	4019/135	8812

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 08/711,339	Applicant(s) BINGGELI ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-137 is/are pending in the application.
- 4a) Of the above claim(s) 48-61, 67, 73-76 and 101-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40, 42-47, 62-66, 68-72 and 77-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/31/96/12/98, +others</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-40 and 42-137 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2006 has been entered.

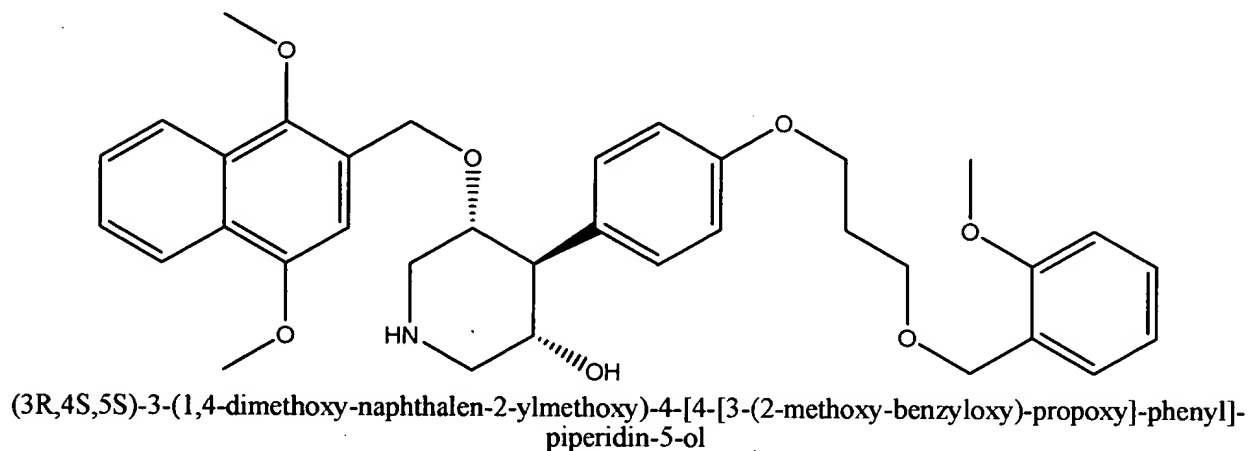
Election/Restrictions

Applicant's election of the species of claim 137 (structural depiction shown below) in the reply filed

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on November 10, 1997 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Elected Species of Instant claim 137

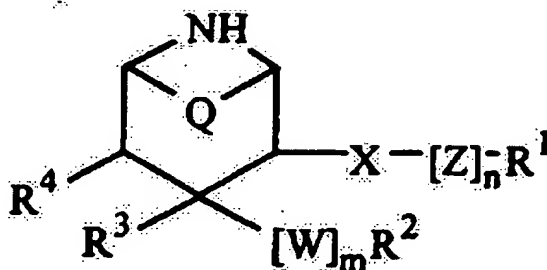


The claims have been examined to the extent that they are readable on the elected species, the compound in instant claim 137. Since no prior art was found on the elected species, the examination was expanded until art was found, in which case, the examination stopped and art has been applied against the claims. Note,

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M.P.E.P. § 803.02. The subject matter of the expanded search, which is inclusive of the elected species of claim 137 and the generic concept identified in the Office Action dated March 23, 1998, is as follows:

Compounds of formula (I)



wherein

R¹ is aryl, optionally substituted;

R² is phenyl or naphthyl, each optionally substituted;

X is O or S;

Z is lower alkylene;

Q is absent;

m is zero (W is absent);

R³ is hydrogen;

R⁴ is OH or hydrogen;

n is 1; and

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all other variables are as defined in the claims.
The claims embraced by the expanded search are claims
1-40, 42-47, 62-66, 68-72 and 77-100.

Subject matter not embraced by the above identified
expanded search and Claims 48-61, 67, 73-76 and 101-136
are withdrawn from further consideration pursuant to 37
CFR 1.142(b) as being drawn to nonelected inventions,
there being no allowable generic or linking claim.
Election was made **without** traverse in the reply filed
on November 10, 1997.

Priority

Receipt is acknowledged of papers submitted under
35 U.S.C. 119(a)-(d).

Since this application was reconstructed under 37
CFR 1.251, it is requested that Applicant re-submit

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copies for the file of the two Swiss applications filed September 7, 1995 and July 26, 1996.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on December 31, 1996, August 12, 1998, March 31, 2000, June 5, 2000, March 3, 2003, February 16, 2006 and July 17, 2006.

Claims 1-40, 42-47, 62-66, 68-72 and 77-100 have been considered to the extent that these claims embrace the elected species and the above indicated expanded search. All other subject matter in these claims has not been considered. The various filed information disclosure statements have also been considered only as they apply to the expanded search indicated above.

Claim Objections

Claims 10 and 62 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-40, 42-47, 62-66, 68-72 and 77-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1, under the definition of T^1 , T^2 , T^3 and T^4 , an "or" should be added before definition (r) for proper Markush language. See claim 2 for same.

In claim 1, under the definition of R^{4a} , an "or" should be added before definition (t) for proper Markush language.

In claim 1, under the definition of Z^1 , an "or" should be added before definition (m) for proper Markush language.

In claim 1, under definition (d) of Z^1 , an "or" should be added after "-N(R^{11})-" for proper Markush language.

In claim 1, under the definition of X^1 , an "or" should be added before definition (e) for proper Markush language.

In claim 1, last line of claim, it appears that something is missing in the expression "or its hydrochloride". It would appear that the expression should be "or its hydrochloride salt".

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Claim 3 lacks antecedent basis from claim 1 since it is not stated in claim 1 that the "aryl" defined by R¹ can be substituted. See claims 6, 7, 10, etc. for same.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 38-40 and 137 are rejected under 35 U.S.C. 101 as claiming the same invention as that of

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claims 1-4, respectively, of U.S. Patent No. 6,051,712.

This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A

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terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 35-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,051,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically described in the patent. See, for example, claim 1 of the patent and instant claim 10.

The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds would possess similar activity to that which is claimed in the patent (i.e., renin inhibiting activity). One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be have rennin inhibiting activity. The

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instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Anthony et al. {U.S. Patent No. 5,891,889}.

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Anthony et al. disclose the compound in column 92, lines 53-54. This compound of Anthony et al. embraced by the instant claimed invention when R^1 represents phenyl; R^2 represents phenyl; X is O; Z is methyl; Q is absent; m is zero (W is absent); R^3 is hydrogen; R^4 is hydrogen; and n is 1. The compound can also be found in the provisional application of Anthony et al. on page 115, lines 12-15. Therefore, Anthony et al. anticipate the instant claimed invention.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The elected species, the compound in instant claim 137, is not allowable. See the rejection of claim 137

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under statutory double patenting over U.S. Patent No.
6,051,712.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read 'Laura L. Stockton', written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

March 12, 2007